MAR 2 0 2008

K080482

510(k) Summary

Page 1 of 3 (2)

ArtroCare Corporation
ArthroCare Irrigation Pump

Manufacturer:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	February 21, 2008

Device Description

Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Trade Name:	ArthroCare Irrigation Pump
Generic/Common Name:	Electrosurgical Device and Accessories

Predicate Devices

• ArthroCare Flow Control Unit	K001904; cleared July 17, 2000

Intended Use

The ArthroCare Irrigation Pump is an accessory, supplied separately, that can be used with the following Electrosurgery Systems for the referenced indications:

- The ArthroCare ENT Coblator Surgery System is indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery.
- The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

K080482

Page 2 of 2

Product Description

The Irrigation Pump is an accessory that may be used with ArthroCare's Electrosurgery Systems. The Irrigation Pump consists of the Irrigation Pump and Flow Control Cable. The ArthroCare Irrigation Pump is designed to automate the flow of conductive media during soft tissue ablation and coagulation where conductive media must be delivered to the treatment site.

Substantial Equivalence

This Special 510(k) proposes a modification in the preformance specifications, ergonomic user interface, and labeling for the ArthroCare Flow Control Unit which was previoulsy cleared under K001904 on July 17, 2000. The indications for use and principal of operation remain the same as in the originally cleared 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2008

ArthroCare Corporation
% Ms. Valerie DeFiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

Re: K080482
Trade/Device Name: ArthroCare Irrigation Pump
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, GXI
Dated: February 21, 2008
Received: February 22, 2008

Dear Ms. DeFiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: ArthroCare Irrigation Pump

510(k) Number: K 080482

Indications for use:

The ArthroCare Irrigation Pump is an accessory, supplied separately, that can be used with the following Electrosurgery Systems for the referenced indications:

- The ArthroCare ENT Coblator Surgery System is indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery.
- The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

Prescription Use (Per 21 CFR 801.109) X OR Over-the-Counter Use ____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080482

x